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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/664,827 09/19/00 ERIKSON

G E1047/20044

EXAMINER

HM22/0718

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ART UNIT

PAPER NUMBER

1655

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/664,827

Applicant(s)
ERIKSON et al.

Examiner
CB Wilder

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 1, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above, claim(s) 26-49 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 50, and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

1. The sequence amendment filed May 11 , 2001 in Paper 6 is acknowledged and has been entered.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-25, 50 and 51 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the Groups I-III would be no serious burden on the Patent Office to examine because the subject matter of the Groups I-III is sufficiently related that a search of the subject matter of the any one group would encompass a search for the subject matter of the other Groups. Applicant concludes that the restriction is improper and should not be maintained. This is not found persuasive because the searches of the different Groups are not coextensive in the art since methods of hybridization and binding assays as claimed in Groups II and III are not necessarily combined or required for multiplex structures. Furthermore, as stated in the Office Action of Paper No. 5, the multiplex structure of Group I can be used in other materially different process besides hybridization methods or binding assay such as e.g., nucleic acid sequencing methods or nucleic acid purification methods or antisense studies or amplification assay or in cross linking studies. The requirement is still deemed proper and is therefore made FINAL.

Objections

3. Claims 1-25 and 50 are objected to because the subject matter of this application (multiplex structure) admits of illustration by a drawing to facilitate understanding of the invention. Applicant

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is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. Claims 1, 3, 4, 6, 20-22 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Sen et al. (5,948,897, September 7, 1999). Regarding claim 1, 3, 4, and 6, Sen et al. teach a purified multiplex structure comprising a first strand containing a first sequence of nucleobases; a second strand containing a second sequence of nucleobases, wherein said second strand is associated with said first strand by Watson-Crick bonding; a third strand containing a third sequence of nucleobases; and a fourth strand containing a fourth sequence of nucleobases, wherein said fourth strand is associated with said second strand and said third strand by Watson-Crick bonding (col. 15, claim 1). Sen et al. further teach wherein the strands comprise DNA or RNA or DNA and RNA (col. 15, claims 6-8, see also figure 2b). Therefore the claimed invention of claims 1, 3, 4 and 6 are anticipated by the reference of Sen et al.

Regarding claims 20-22, Sen et al. teach wherein the multiplex structure is bound to a solid support. Sen et al. teach two types of solid support for the multiplex structure. One of the support being electrically conductive and the other support not electrically conductive (col. 11, lines 35-55).

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Regarding claim 51, Sen et al. teach an electrical circuit for the multiplex structure (col. 11, lines 35-55). Therefore, the claimed invention of claims 1, 3, 4, 6, 20-22 and 51 are anticipated by the reference of Sen et al.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 7, 8, 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sen et al. Regarding claims 7, 8 and 10, Sen et al. teach a multiplex structure having four strands wherein at least two of the strands are associated together by Watson-Crick bonding to form a quadruplex structure. Sen et al. further teach wherein the strand are capable of aligning in an anti-parallel (col. 15, lines 17-22). The preceding rejection is based on judicial precedent following *In re Fitzgerald*,

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205 USPQ 594 because the reference is silent with regards to which of the strands is placed in a major groove or in a minor groove. However, the claimed features are deemed inherent in the teaching of the multiplex structure of Sen et al. as disclosed in figures 2 and 7. The burden is on Applicant to show that the claimed multiplex structure is either different or nonobvious over those of Sen et al.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 4-6, 11-19, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. (5,451,503, September 1995). Regarding claims 1, 4, 6, 15, and 24 Hogan et al. teach

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a multiplex structure comprising a first, second, third and fourth strand associated with each other via monomer-to monomer interactions (Figures 6G, 6H and 21). Hogan et al. further teach wherein the strands are selected from the group consisting of DNA, modified DNA, RNA, modified RNA or various combinations thereof (col. 6, 11-14). Hogan et al. additionally teach wherein the strands are about 8-30 or about 8-100 base pairs long (col. 2, lines 53-54). The multiplex structure of Hogan et al. differs from the instant invention in that Hogan et al. do not expressly teach that the strands are associated with each other by Watson-Crick bonding. However, Hogan et al. do teach that the strands are formed from the bonding of specific base pairs called complementary molecules, e.g., between adenine and thymine and adenine and uracil or guanine and cytidine (col. 1, lines 14-21 and figure 21). Hogan et al. exhibits this bonding in Figure 21. Therefore, since it is known in the art that Watson-Crick base pairing is the specific hydrogen-bonding between purines and pyrimidines in double stranded nucleic acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the strands in the multiplex structure of Hogan et al. are associated with each other via Watson-Crick bonding based on the teachings above and the bonding of the nucleobases in figure 21 of the Hogan et al. reference.

Regarding claim 5, Hogan et al. disclose wherein each strand comprise an uncharged backbone (Figure 21).

Regarding claim 11, Hogan et al disclose wherein each nucleobase binds to its complementary nucleobase. In other words, the nucleobase binds to no more than two other nucleobase (Figure 21).

Regarding claim 12, Hogan et al. disclose wherein no strand is contiguous with another strand (Figure 21).

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Regarding 13, Hogan et al. disclose wherein the multiplex structure is substantially free of Hoogsteen bonding (Figure 21).

Regarding claim 14, Hogan et al. disclose wherein the multiplex structure is substantially free of G-G quartets (Figure 21).

Regarding claim 16, Hogan et al. teach wherein the strands of the multiplex structure are naturally occurring DNA which encompasses genomic DNA, modified DNA, RNA, modified RNA, or any combination thereof (col. 6, lines 11-21).

Regarding claims 17, Hogan et al. teach a multiplex structure comprising a first, second, third and fourth strand associated with each other via monomer-to monomer interactions such as Watson-Crick base bonding (Figures 6G, 6H and 21). Hogan et al. further teach wherein the strands are selected from the group consisting of naturally occurring DNA, modified DNA, naturally occurring RNA, modified RNA or various combinations thereof (col. 6, 11-14) and wherein one of the strands is a target strand (figure 21). Hogan et al. differs from the instant invention in that Hogan et al. do not expressly teach wherein the third and fourth strands include a haplotype in genomic DNA. However, it is generally known in the art that naturally occurring nucleic acids are a diverse collection of nucleic acid with numerous sequence variations. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the multiplex structure of Hogan et al. comprise strands having haplotypes based on general knowledge well known in the art that naturally occurring nucleic acids or genomic nucleic acids are diverse and comprise numerous sequence variations.

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Regarding claim 18, Hogan et al. disclose wherein the strands are capable of being amplified by PCR (Example 9 and 10).

Regarding claim 19, Hogan et al. teach wherein the multiplex structure is free of a solid support (in solution) (col. 8, lines 57-65).

Regarding claim 23, Hogan et al. disclose wherein at least one of the strands of the multiplex structure further comprises a therapeutic agent (col. 25, beginning at line 25 to col. 26, line 9).

Regarding claim 25, Hogan et al. disclose wherein the fourth strand contains about 58% purine bases and about 39% pyrimidine bases (Figure 21).

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The Examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

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Cynthia B. Wilder, Ph.D. *Cynthia Wilder*

July 13, 2001

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STEPHANIE W. ZITOMER
PRIMARY EXAMINER